SAGE April 2016

Preempting and responding to vaccine supply shortages

Introduction

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Objectives of the session

• Present the situation regarding shortages, including main reasons behind shortages

• Present initiatives in place to pre-empt and respond to these shortages

• Discuss the role of WHO on this issue, within the scope of the WHA resolution 68.6 on the GVAP urging WHO to address factors that can detrimentally impact vaccine availability.
Outline of the introduction

1. Background

2. What are the main causes?

3. What is being done?
1. Background
In 2015, stories about vaccine shortages have multiplied, leading to increased attention on vaccine security.

Vaccine security: “the sustained, uninterrupted supply of affordable vaccines of assured quality”¹

¹ – UNICEF definition
Several vaccines are currently in short supply or at risk of a shortage

Vaccines in the WHO Model List of Essential Medicines:

<table>
<thead>
<tr>
<th>Traditional vaccines</th>
<th>Newer vaccines</th>
<th>Vaccines with specific recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BCG</strong></td>
<td><strong>MR, MMRV</strong></td>
<td><strong>aP-containing</strong></td>
</tr>
<tr>
<td>DTP</td>
<td><strong>tOPV</strong></td>
<td><strong>IPV</strong></td>
</tr>
<tr>
<td>* tOPV</td>
<td><strong>aP</strong>-containing</td>
<td><strong>IPV</strong></td>
</tr>
<tr>
<td><strong>aP</strong>-containing</td>
<td><strong>IPV</strong></td>
<td><strong>HepA</strong></td>
</tr>
<tr>
<td><strong>IPV</strong></td>
<td><strong>HepA</strong></td>
<td><strong>Japanese Encephalitis</strong></td>
</tr>
<tr>
<td><strong>HPV</strong></td>
<td><strong>HepA</strong></td>
<td><strong>Cholera</strong></td>
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<tr>
<td><strong>PCV</strong></td>
<td><strong>HepA</strong></td>
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</tr>
<tr>
<td><strong>Rotavirus</strong></td>
<td><strong>HepA</strong></td>
<td></td>
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<tr>
<td><strong>Yellow Fever</strong></td>
<td><strong>HepA</strong></td>
<td></td>
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<tr>
<td><strong>Meningococcal</strong></td>
<td><strong>HepA</strong></td>
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<tr>
<td><strong>Japanese Encephalitis</strong></td>
<td><strong>HepA</strong></td>
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<tr>
<td><strong>Cholera</strong></td>
<td><strong>HepA</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Legend:</th>
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<tbody>
<tr>
<td>Red: Known shortages in several countries and regions</td>
</tr>
<tr>
<td>Orange: Known shortages in a few countries, or vaccine at risk of shortage (eg. with 2 or less manufacturers)</td>
</tr>
</tbody>
</table>

- 15 out of 25 vaccines in shortage or at risk of a shortage (60%).
- Issues for newer vaccines are mainly linked to mono/duopoly situations.
- Issues are more complex for traditional vaccines and vaccines with specific recommendations.
- Other biologicals also in shortages (e.g. diphtheria antitoxin, snake antivenoms).

Vaccines with no known issues:

- Measles; Hib; HepB; DTP-HepB-Hib; TT; Td; Rabies; Typhoid; MMR; Seasonal influenza

Source: WHO Model List of Essential Medicines April 2015, UNICEF SD, communication with regions, press releases
Vaccine shortages can lead to stockouts

**Shortage**

There is a vaccine shortage when a vaccine cannot be obtained by a country in sufficient amount to cover the full population at risk.

- Global shortage
- Country shortage

**Stockout**

There is a stockout of vaccine when stocks at the national or district levels have been depleted. Vaccines are not available to anyone anymore.

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Global concerns over shortages are being brought to WHO’s governing bodies

**MEDICINES**

138th WHO Executive Board
January 2016

69th World Health Assembly
May 2016

WHO Member States underscored the need for public health approach to world drug problem

**VACCINES**

68th World Health Assembly
May 2015

Resolution 68.6 on Global Vaccine Action Plan (GVAP):
“[…] the establishment of effective and sustainable vaccine production, supply, procurement and delivery systems is essential to ensure access to all the necessary vaccines of assured quality at the right time”

Preparation of a resolution on “Addressing the global challenges of medicines shortages”
2. What are the main causes?
There are several known causes behind shortages

1. **SUPPLY**
   - Factors limiting availability
     - Production issues
     - Limited supplier base & global capacity

2. **DEMAND**
   - Factors limiting access
     - Little demand flexibility
     - Lack of demand predictability

3. **INFORMATION**
   - Factors limiting supply / demand communication
     - Limited supply information
     - Limited demand information
     - Lack of timely communication

Sources: Goldstein 2005; Offit 2005; M.S. Coleman 2005 & 2006; Callender 2006; Danzon 2005 & 2011; Hitchcock 2007; Light 2009; Smith 2011; Woodcock 2012; Gordon Douglas 2013; Congeni 2014; Yen 2015; Cacciatore 2016; BIOTECAnada 2010; US CDC website; US FDA website; MesVaccins.net; UNICEF; V3P database; WHO; WHO regional and country consultations 2014-2015; MIC task Force; GVAP Secretariat Report 2015; Press articles; Oanda.com; discussions with experts; discussions with Industry representatives
Causes of shortages: BCG example

1. SUPPLY
Factors limiting availability

- 4 manufacturers with prequalified products in 2015 (+1 in 2016)
- Technical issues at manufacturing sites
- Low market attractiveness

2. DEMAND
Factors limiting access

- Fluctuations in demand
- Lack of knowledge on alternative solutions

3. INFORMATION
Factors limiting supply / demand communication

- Countries expressing concerns about lack of availability
- Countries not informed about upcoming risk of shortage

Main area of concern

Sources: Goldstein 2005; Offit 2005; M.S. Coleman 2005 & 2006; Callender 2006; Danzon 2005 & 2011; Hitchcock 2007; Light 2009; Smith 2011; Woodcock 2012; Gordon Douglas 2013; Congeni 2014; Yen 2015; Cacciatore 2016; BIOTECanada 2010; US CDC website; US FDA website; MesVaccins.net; UNICEF; V3P database; WHO; WHO regional and country consultations 2014-2015; MIC task Force; GVAP Secretariat Report 2015; Press articles; Oanda.com; discussions with experts; discussions with Industry representatives
# Causes of shortages: aP containing vaccines example

## 1. SUPPLY
Factors limiting availability

- Only 2 manufacturers (0 prequalified)
- Complex manufacturing process. Long production time. Manufacturing delays and quality testing issues

## 2. DEMAND
Factors limiting access

- Safety concerns leading countries to switch from wP-containing vaccines to aP-containing vaccines
- Steady increase in global demand, particularly coming from MICs

## 3. INFORMATION
Factors limiting supply / demand communication

- Lack of information on demand evolution, leaving manufacturers with little time to ramp up capacity
- Lack of communication on reasons for supply issues and timeline for re-supplying leading to ad-hoc mitigation actions and distrust

### Main area of concern

Sources: Goldstein 2005; Offit 2005; M.S. Coleman 2005 & 2006; Callender 2006; Danzon 2005 & 2011; Hitchcock 2007; Light 2009; Smith 2011; Woodcock 2012; Gordon Douglas 2013; Congeni 2014; Yen 2015; Cacciatore 2016; BIOTECanada 2010; US CDC website; US FDA website; MesVaccins.net; UNICEF; V3P database; WHO; WHO regional and country consultations 2014-2015; MIC task Force; GVAP Secretariat Report 2015; Press articles; Oanda.com; discussions with experts; discussions with Industry representatives
3. What is being done?
There are several actors working on supply and demand

<table>
<thead>
<tr>
<th>Actor</th>
<th>Demand Management</th>
<th>Operations/Procurement</th>
<th>Supply Management</th>
<th>Long-term Supply</th>
<th>Information &amp; communication</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Policy/Introduction</td>
<td>Forecasting</td>
<td>Delivery</td>
<td>Supply Management</td>
<td>Tendering</td>
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<tr>
<td>BMGF/its technical grantees</td>
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<tr>
<td>Gavi</td>
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<td>UNICEF</td>
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<td>WHO</td>
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<td>PAHO</td>
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</tbody>
</table>

- Several global actors across areas
- Most actors have a specific focus (e.g. PAHO on PAHO countries, Gavi on Gavi countries/vaccines)

Size of circle indicates level of focus

Legend:
- Gavi
- Non-Gavi
- PAHO

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Supply/demand risk is highest in self-procuring Middle Income Countries (MICs)

Country demand vs. supply risk:

Size of circle indicates demand volume

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</thead>
<tbody>
<tr>
<td>Support Type</td>
<td>Gavi Alliance</td>
<td>UNICEF Procurement</td>
<td>PAHO Procurement</td>
<td>Self-procuring</td>
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</tbody>
</table>

Self-procuring MICs have mixed prospects. With several countries vulnerable to markets not being able to meet their demand at affordable prices.
Outline of the session

- Dealing with vaccine shortages
  - Oleg Benes, WHO EURO: Impact of shortages and solutions set up by countries
  - Michael Sulzner, European Commission DG SANTE: Vaccine shortages: Improving cooperation, communication and management in the European Union
  - Ann Ottosen, UNICEF SD: Global operational procurement planning and long-term strategic supply security

- Statements & discussion
Preempting and responding to vaccine supply shortages

Thank you!